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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/099,822      | 03/16/2002  | Sheldon S. Chang     |                     | 2710             |

7590

12/19/2003

Prof. Sheldon S. Chang  
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| EXAMINER |
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MACHUGA, JOSEPH S

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| ART UNIT | PAPER NUMBER |
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3762

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DATE MAILED: 12/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/099,822

Applicant(s)

CHANG, SHELDON S.

Examiner

Joseph S. Machuga

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_ 6) ☐ Other: .

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Several of the terms used in the claims are indefinite. "Installed" as used in claims 1, 2, 7 and 8 is indefinite since it refers to its location as opposed to the function of sending electrical pulses. "Clinical signals" as used in claims 3, 4, 9 and 10 is also indefinite since it refers to the measurement of biological parameters. "Prototype" used in claims 5, 6, 11 and 12 is vague. Claim 13 should clearly recite the two pumps.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Leachman, Jr. #3911898.

Leachman, Jr. discloses a ventricular assist device having a pump (10), pacemaker (110) and pressure sensor (50.) This disclosed device would provide for all of the features recited in the claims.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 3-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arnold #4995857 in view of Aldrich #6585635 and Freed et al #6132363.

7. Arnold discloses a ventricular assist device having a pump and pressure sensor (32.) Not disclosed by this reference is the pacing electrode and the programming features of claims 5 and 6. Aldrich teaches adding a sensing and pacing electrode to a heart assist device to monitor/pace or treat the heart (column 5, lines 17-27.) Freed et al teaching adding programmable systems to a heart assist device to make the device adaptable to changing conditions such as the patient's clinical status, medications, blood flow, volume or pressure, etc. (column 5, lines 13-19.)

8. Given these teachings it would have been obvious to one of ordinary skill in the art to add sensing and pacing electrodes to Arnold's device to treat irregular heart beats as taught by Aldrich. To add a programmable system to Arnold's device to make it adaptable would have been obvious given Freed et al's teaching.

9. Claims 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leachman, Jr. #3911898 in view of Summers et al #5112349.

Leachman, Jr. discloses a ventricular assist device having a pump (10), pacemaker (110) and pressure sensor (50.) This disclosed device would provide for all of the features recited in the claims except the linear flow pump.

Summers et al discloses a heart assist device. The reference teaches that a linear flow blood pump is idea for this environment because it produces no turbulence, which is idea for shear sensitive material such as blood.

Given Summers teaching, it would have been obvious to one of ordinary skill in the art to use a linear flow blood pump in place of pump (10) in Leachman, Jr.'s device.

10. Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leachman, Jr. #3911898 in view of Summers et al #5112349 as applied to claim 7 above, and further in view of Freed et al.

11. Freed et al teaching adding a programmable systems to a heart assist device to make the device adaptable to changing conditions such as the patient's clinical status, medications, blood flow, volume or pressure, etc. (column 5, lines 13-19.) Given this teaching it would have been obvious to one of ordinary skill in the art to a programmable system to the system of the proposed combination to make it adaptable given Freed et al's teaching.

12. Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leachman, Jr. #3911898 in view of Summers et al #5112349 as applied to claim 7 above, and further in view of Phillips #4955856.

Phillips teaches adding two pump to a ventricular assist device to assist in pumping blood through both ventricles. Given this teaching it would have been obvious to add a second pump to the device of the proposed combination to assist in pumping blood through both ventricles. To control the pumps independently by varying the magnitude and frequency of the current would have been obvious given that Summers et al uses electric motors.

13. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Leachman, Jr. #3911898 in view of Summers et al #5112349 and Freed et al as applied to claims 11 and 12 above, and further in view of Lewis et al.

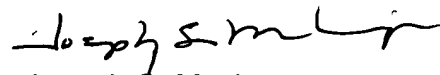
14. Lewis et al teaches locating the biological interface below the skin to avoid contamination. To locate the interface of the proposed combination in this same location would have been obvious to one of ordinary skill in the art to avoid contamination.

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Feindt et al, Reinhardt et al and Grandjean are cited to should assist devices with pacing electrodes. Jarvik and Spence are cited to show related systems.

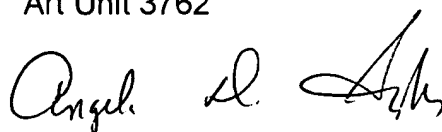
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph S. Machuga whose telephone number is 703-305-6184. The examiner can normally be reached on Monday-Friday; 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-306-4520.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1148.

  
Joseph S. Machuga  
Examiner  
Art Unit 3762

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ANGELA D. SYKES  
SUPERVISORY PATENT EXAMINER  
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